

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

CIVIL ACTION NO. 04-mc-10128-GAO

ALLEN A. MITCHELL, M.D., SAMUEL M. LESKO, M.D.,
and TRUSTEES OF BOSTON UNIVERSITY,
Plaintiffs

v.

KERRY LANGSTAFF and BRADSHAW LANGSTAFF,
Individually, and on behalf of
KAITLIN SIERRA LANGSTAFF, a minor child,
Defendants

CIVIL ACTION NO. 04-mc-10137-GAO

KERRY LANGSTAFF, et al.,
Plaintiffs

v.

ALLEN A. MITCHELL, M.D., SAMUEL M. LESKO, M.D., and
TRUSTEES OF BOSTON UNIVERSITY,
Defendants

MEMORANDUM AND ORDER

June 25, 2004

O'TOOLE, D.J.

The pending discovery disputes arise from a product liability action pending in the United States District Court for the Northern District of California. The plaintiffs in that action, Kerry and Bradshaw Langstaff, have served subpoenas duces tecum on non-party witnesses, Drs. Allen A. Mitchell and Samuel M. Lesko and the custodians of records for Dr. Mitchell and the Slone Epidemiology Center at Boston University ("Slone"). In this Court, Drs. Mitchell and Lesko have moved to quash the subpoenas seeking their deposition testimony and the production of documents (Civil Action No. 04-mc-10128), and the Langstaffs have moved to compel the production of

documents from the custodians of records for Dr. Mitchell and Sloane (Civil Action No. 04-cv-10137).

After hearing and consideration of the parties' submissions, I conclude that Drs. Mitchell and Lesko's motion to quash ought to be granted, and the Langstaffs' motion to compel ought to be denied.

I. **Background**

Pediatric ibuprofen was available by prescription beginning in 1989. From 1991 to 1993, Drs. Mitchell and Lesko, working at the Sloane Epidemiology Center at Boston University, conducted a clinical trial to assess the risks of adverse events following the use of pediatric ibuprofen to treat children with fevers. McNeil Consumer Products Co., a manufacturer of pediatric ibuprofen, provided financial support for the study, which became known as the Boston University Fever Study or the Boston Fever Study. The study was designed to gather safety data on the use of pediatric ibuprofen with the goal of obtaining Food and Drug Administration approval for its over-the-counter use. The results of the study were published in the Journal of the American Medical Association ("JAMA"). McNeil's support of the study was disclosed in the JAMA article.

More than 1,700 physicians participated in the study, and more than 84,000 children with fevers were randomly assigned to receive either ibuprofen or the control drug, acetaminophen. The study was designed to determine whether use of pediatric ibuprofen increased the risk, relative to acetaminophen, of hospitalization for gastrointestinal bleeding, renal failure, anaphylaxis, or Reye's Syndrome. Relying on the results of the study, Drs. Mitchell and Lesko concluded that the risks of certain adverse reactions were not increased following the use of pediatric ibuprofen, as compared

with acetaminophen. The FDA ultimately approved for over-the-counter use McNeil's pediatric ibuprofen, which was sold as Children's Motrin.

The present discovery dispute stems from a product liability action the Langstaffs brought in the Northern District of California after their minor daughter used Children's Motrin and then suffered and died from a rare adverse skin reaction known as Stevens-Johnson Syndrome/Toxic Epidermal Necrolysis (SJS/TEN). The defendants in that action are McNeil and Johnson & Johnson, Inc., its corporate parent.

In November 2003, the Langstaffs served subpoenas duces tecum on the custodian of records for Slone Epidemiology Center and the custodian of records for Dr. Mitchell, the director of the center, seeking twenty-five categories of documents concerning the Boston Fever Study. Slone, Mitchell, and Boston University objected to the subpoenas, invoking Fed. R. Civ. P. 45(c), and the Langstaffs have moved to compel compliance with those subpoenas.

Further, in April 2004, the Langstaffs served subpoenas duces tecum on Drs. Mitchell and Lesko, seeking the production of a subset of the categories of documents that they sought in the custodian of records subpoenas and also seeking deposition testimony. Mitchell, Lesko, and Boston University have moved to quash the subpoenas.

II. Discussion

A. Mitchell and Lesko's motion to quash

Mitchell and Lesko seek the protection of Fed. R. Civ. P. 45(c)(3)(B)(ii), which states:

If a subpoena . . . requires disclosure of an unretained expert's opinion or information not describing specific events or occurrences in dispute and resulting from the expert's study made not at the request of any party . . . the court may, to protect a person subject to or affected by the subpoena, quash or modify the subpoena or, if the party in whose behalf the subpoena is issued shows a substantial need for the

testimony or material that cannot be otherwise met without undue hardship and assures that the person to whom the subpoena is addressed will be reasonably compensated, the court may order appearance or production only upon specified conditions.

Cases construing and applying the rule are sparse, and there is no authoritative interpretation binding in this circuit. The few reported cases dealing with the rule may provide some useful guidance, but they must be considered in light of other bases for construction, such as the ordinary or evident meaning of the rule itself, the purpose for its inclusion (e.g., the "evil" to be avoided), and the practical problems that various alternative interpretations present.

The plain language of the rule indicates that it affords "unretained experts" some protection against discovery. The rule was promulgated in 1991 in response to the "growing problem" of "the use of subpoenas to compel the giving of evidence and information by unretained experts." Fed. R. Civ. P. 45 advisory committee's notes, 1991 amend. The advisory committee recognized that the "compulsion to give evidence may threaten the intellectual property of experts denied the opportunity to bargain for the value of their services." Id. Thus, the rule was intended to provide unretained experts the right to "withhold their expertise" until the party seeking it makes an adequate showing that their testimony should be compelled. Id.

Initially, it is necessary to determine whether Mitchell and Lesko are "unretained experts" for purposes of the rule. The rule is expressly concerned with the disclosure of evidence "resulting from the expert's study made not at the request of any party." The scope of the phrase "made not at the request of any party" and, consequently, an expert witness's status as "retained" or "unretained" should be determined in the context of the Federal Rules of Civil Procedure generally and with reference to Fed. R. Civ. P. 26 in particular. Rule 26(a)(2)(B) refers to "a witness who is

retained or specially employed to provide expert testimony in the case,” and Rule 26(b)(4)(B) refers to “an expert who has been retained or specially employed by another party in anticipation of litigation or preparation for trial.” In both instances, Rule 26 links the status of an expert as “retained” to the particular litigation at hand, and does not use the term in a broader sense to include a prior relationship with an expert not connected with the conduct of the pending litigation. In other words, the fact that a party had previously retained an expert for some purpose does not make the expert “retained” within the meaning of either Rule 26 or Rule 45.¹

Here, Mitchell and Lesko are “unretained experts” with respect to the pending product liability action. While they have previously conducted scientific research that McNeil, a defendant in the pending action, supported, they have not been “retained or specially employed” with respect to the pending action. They are “unretained experts” eligible to invoke the protections of Rule 45(c)(3)(B)(ii).

The next step is to determine how much protection, if any, the rule affords them. The rule is expressly concerned with a subpoena that “requires disclosure of an unretained expert’s *opinion* or *information* not describing specific events or occurrences in dispute and resulting from the expert’s study made not at the request of any party.” Fed. R. Civ. P. 45(c)(3)(B)(ii) (emphasis added). The rule’s protection of both an unretained expert’s “opinion” and “information” is consistent with Fed. R. Evid. 702, which governs the admissibility of expert testimony. Rule 702 indicates that testimony concerning “scientific, technical, or other specialized knowledge” may be given “in the form of an opinion or otherwise.” (Emphasis added.) In other words, expert evidence

¹ It is therefore unnecessary to decide whether providing financial or other support for the conduct of a study based on clinical trials amounts to “retaining” the persons conducting the study.

may, but need not, involve testifying to an “opinion.” It may also involve explaining “information” that is “scientific, technical, or . . . specialized,” even if no opinion is expressed. Consequently, testimony concerning assumptions, decisions, processes, and protocols involved in scientific research would generally be evidence governed by Rule 702 to be presented only by an expert witness. Such “information” would be afforded protection under Rule 45.

Rule 45, however, does not protect all “information” that is sought through the testimony of an unretained expert; it offers no protection to an unretained expert’s “information” “describing specific events or occurrences in dispute,” and such evidence may be compelled by subpoena. Simply put, Rule 45 may be read to distinguish between what may be called “expert evidence” – which would be governed by Rule 702 and would include both “opinions” and “information” that is “scientific, technical, or . . . specialized” – and “non-expert evidence” – which would include fact evidence such as information “describing specific events or occurrences in dispute.” Rule 45(c)(3)(B)(ii) offers protection to an unretained expert whom a party seeks to compel to give expert evidence but offers no protection to the extent an unretained expert is called upon to give non-expert evidence.

Applying these principles to the present motions leads to the conclusion that some – and perhaps much – of the evidence that the Langstaffs seek from Mitchell and Lesko is expert evidence concerning the Boston Fever Study, and as such it is within the protections offered by Rule 45(c)(3)(B)(ii). The protected expert evidence would include the doctors’ scientific opinions as well as evidence concerning assumptions, decisions, processes, and protocols concerning the study. At the same time, at least some of the evidence the Langstaffs seek is non-expert evidence and not protected by the rule. The non-expert evidence would include, for example, information concerning

the business or financial relationship between McNeil and Mitchell, Lesko, Slone and/or Boston University, the names of doctors who participated in the study, and the merely historical, non-scientific content of advisory committee meetings.

The conclusion that some of the evidence the Langstaffs seek is within the protections of the Rule and other evidence sought is not protected does not end the inquiry. As to evidence that is protected, the Langstaffs may still be entitled to the discovery if they can demonstrate a "substantial need for the testimony or material that cannot be otherwise met without undue hardship" and if the expert witnesses are "reasonably compensated" for their services. Fed. R. Civ. P. 45(c)(3)(B). As to evidence that is not protected by that rule, the third-party subpoena may nevertheless be quashed or modified if it imposes an "undue burden" on the prospective witnesses. Fed. R. Civ. P. 45(c)(3)(A)(iv).

The Langstaffs have not shown a "substantial need" to compel Mitchell and Lesko to disclose protected expert evidence. At the hearing, the Langstaffs' counsel indicated that their product liability action against McNeil is based on a failure-to-warn theory. In brief, they say that when pediatric ibuprofen was available only by prescription, it was sold with a warning that advised of the risk of skin disorders such as the one suffered by the Langstaffs' daughter. However, when the FDA approved over-the-counter use of pediatric ibuprofen, it did not require a warning concerning the risk of skin disorders. McNeil used the results of the Boston Fever Study to support its application to the FDA, and the Langstaffs suggest that the study's findings, including the explicit or implicit minimization of the risk of skin disorders, played a part in the FDA's decision to not require a warning concerning certain skin disorders. Now the Langstaffs seek further discovery concerning

the study to determine what it revealed or should have revealed, or perhaps (to take a darker view) what it concealed, concerning the risk of skin disorders.

However, it is not apparent why further discovery concerning the conduct of the Boston Fever Study is "reasonably calculated to lead to the discovery of admissible evidence" in the Langstaffs' action against McNeil. See Fed. R. Civ. P. 26(b)(1). Slone, Boston University, Mitchell, and Lesko are not parties to that action, and evidence tending to impeach the soundness of their study or its conclusions is not, by itself, directly probative of tortious behavior by McNeil.

At the hearing, the Langstaffs' counsel suggested they seek further discovery to determine what McNeil knew about the conduct of the study and to test their hypothesis that McNeil improperly influenced the study in some way that was favorable to McNeil and ultimately lead to the FDA's decision to not require a warning of the risks of skin reactions from the use of pediatric ibuprofen. For example, the Langstaffs would like to know: what were the guidelines for the study and who developed them; why did the study focus on only four reactions; was that decision based on science or McNeil's influence; and did McNeil exert undue pressure that impacted the researchers' ability to properly measure the risk of certain reactions?

The fact that the Langstaffs are curious about the answers to such questions only explains why they seek the discovery, not why they should be allowed to obtain it. To justify the discovery of protected expert evidence, the "substantial need" for the evidence must be more than hypothetical or speculative. It must be shown – to some degree – to be actual. The Langstaffs, however, have not met their burden to show an actual need for the requested discovery.

It appears that in the pending case McNeil has produced large quantities of documents concerning the conduct of the study and McNeil's connection to it, as well as documents that were submitted to the FDA concerning its approval of over-the-counter use of pediatric ibuprofen.² As a result, the Langstaffs have had significant opportunity to test their hypothesis that McNeil's liability for failure to warn of adverse reactions can be tied to its putative improper influence of the study.

It is not inappropriate to expect that at this stage, after the considerable discovery that has been exchanged to date concerning the study, the Langstaffs would proffer some evidence tending to support their hypothesis that McNeil and/or the doctors may have acted improperly. The record before me reveals no such evidence, and there is no reason to believe that further discovery will advance their claim beyond mere speculation. Accordingly, they have not satisfied their burden to overcome the protection afforded by Rule 45(c)(3)(B)(ii).³

In addition, disclosure of non-expert evidence that is not protected by Rule 45(c)(3)(B)(ii) would impose an "undue burden" on Mitchell and Lesko and thus qualifies for protective relief under Rule 45(c)(3)(A)(iv). As noted above, Rule 26(b)(1) permits "discovery regarding any matter, not privileged, that is relevant to the claim or defense of any party" so long as it "appears reasonably calculated to lead to the discovery of admissible evidence." While that rule is broad, it is not

² Much of what the Langstaffs now seek from Mitchell and Lesko is duplicative of discovery they have already requested from McNeil.

³ The advisory committee notes to the 1993 amendments to Rule 45 state that "the court's discretion in these matters should be informed by" the factors described in Kaufman v. Edelstein, 539 F.2d 811, 822 (2d Cir. 1976). After considering those factors, I conclude that they do not require a different result here. It should be noted that the Kaufman factors are not binding, but merely are to "inform" the decision, and the decision must ultimately be just in light of the Langstaffs' proffered need for the discovery and the burden to be imposed on the unretained expert witnesses.

limitless, and Rule 26(c) permits me to "make any order which justice requires to protect a party or person from annoyance, embarrassment, oppression, or undue burden or expense." As I have heard only these discovery disputes and have no knowledge or familiarity with the entire underlying action beyond what is described in the materials submitted here, I am less well suited than the court in the Northern District of California for determining the relevance of the requested discovery. Nevertheless, on these motions that task falls to me, and I must determine what is just in these circumstances.

As unretained experts, Mitchell and Lesko have been involuntarily summoned to become involved in someone else's dispute. The Langstaffs seek to impose on them a burden to comply with their discovery requests; however, there is no basis in fact to believe that the information sought will be relevant to the Langstaffs' claims against McNeil. Speculation or suspicion that something might turn up is not enough to answer Mitchell and Lesko's complaint that compliance with the subpoenas will be, in the standard-setting language of the Rules, "undue." This is especially true where a significant portion of the evidence that is sought, what I have described as expert evidence, is protected by Rule 45(c)(3)(B)(ii), and there is no obvious or efficient way to separate the protected evidence from the non-protected evidence (or what I have described as non-expert evidence). Any line drawing, whether for purposes of depositions or production of documents, would likely increase, not decrease, the burden imposed on these witnesses.

Accordingly, Mitchell and Lesko's motion to quash the subpoenas duces tecum is granted.

B. **The Langstaffs' motion to compel**

The Langstaffs have also served subpoenas duces tecum on the custodians of records of Slone and Dr. Mitchell. Those subpoenas sought twenty-five categories of documents that were similar to the requests made to Mitchell and Lesko and similar to discovery already sought from McNeil.

Slone and Mitchell objected to the subpoenas, invoking Rule 45(c)(2)(B) which permits a person to serve written objections to a subpoena within fourteen days after service of the subpoena. The Langstaffs did not receive the written objections, however, until the fifteenth day, and they now argue that Slone and Mitchell, by their tardy response, have waived any objections. The argument is not persuasive. While it might be prudent not to excuse lightly a failure to comply with the time periods set by the rules of procedure, to penalize the subpoena recipients for a response that was a day late in this instance would be unjust, where it appears that the Langstaffs' counsel had earlier notice that Slone and Mitchell would object to the subpoenas, even if the formal objections were a little late in coming. Accordingly, I do not deem the objections to have been waived, and I will consider the motion to compel and objections on the merits.

For the reasons discussed above, I conclude that the motion to compel ought to be denied. First, some of the information sought from the custodians of record is the same as the expert evidence sought in the subpoenas served on Mitchell and Lesko and, for the reasons discussed above, is similarly protected under Rule 45(c)(3)(B)(ii). The balance of the information sought is not discoverable because the Langstaffs have not demonstrated a sufficient need for it that would justify imposing an undue burden on the non-party witnesses, also as discussed above.

III. **Conclusion**

Mitchell and Lesko's motion to quash is GRANTED, and the Langstaffs' motion to compel is DENIED.

It is SO ORDERED.

June 25, 2004
DATE

Kaz R. O'Connell
DISTRICT JUDGE